PATIENT INFORMATION LEAFLET

OSTEONATE

SCHEDULING STATUS:

S3

OSTEONATE 70 mg tablets

Alendronic acid

OSTEONATE 70 mg is sugar-free and essentially 'sodium free'.

Read all of this leaflet carefully before you start taking OSTEONATE 70 mg

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other healthcare provider.
- OSTEONATE 70 mg has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What OSTEONATE 70 mg is and what it is used for
2. What you need to know before you take OSTEONATE 70 mg
3. How to take OSTEONATE 70 mg
4. Possible side effects
5. How to store OSTEONATE 70 mg
6. Contents of the pack and other information

1. What OSTEONATE 70 mg is and what it is used for

OSTEONATE 70 mg contains alendronate, part of a group of medicines called non-hormonal medicines known as bisphosphonates.

It helps to rebuild bone and makes bone less likely to fracture.

OSTEONATE 70 mg is prescribed to treat osteoporosis (thinning of the bone) after menopause in women and also to treat osteoporosis in men. It also reduces the risk of spine and hip fractures.

2. What you need to know before you take OSTEONATE 70 mg

Do not take OSTEONATE 70 mg:

- if you are hypersensitive (allergic) to alendronate or any of the other ingredients of OSTEONATE 70 mg (see section 6)
- if you have severe kidney disease
- if you are suffering from any medical problems, especially a history of oesophageal (food pipe) and digestive disorders
- if you are not able to stay in an upright position for at least 30 minutes after taking OSTEONATE 70 mg
- if you are a child or adolescent
- if you are pregnant or breastfeeding your baby
- if your doctor has told you that you currently have low levels of calcium in your blood.

Warnings and precautions

Take special care with OSTEONATE 70 mg:

- if you have poor dental health, gum disease, a planned dental extraction or you do not receive routine dental care
- your doctor may require you to visit your dentist before starting treatment, especially if you have other medical conditions such as cancer, you are undergoing chemotherapy or radiotherapy, you are taking corticosteroids (such as prednisone or dexamethasone), you are or have been a smoker
- you should avoid dental procedures or surgery while taking OSTEONATE 70 mg

- if you develop chronic ear pain or ear infections
- if you have, or have recently had, any swallowing or digestive problems, your doctor has told you that you have Barrett's oesophagus (a condition associated with changes in the cells that line the lower oesophagus), or you have recently had surgery on the gastro-intestinal tract
- stop taking OSTEONATE 70 mg tablets immediately and consult your doctor if you develop the following symptoms of throat disease:
    - difficulty or pain swallowing
    - chest pain or new or worsening heartburn
- the risk of developing the above side effects can be reduced if you swallow OSTEONATE 70 mg with a full glass of water and/or if you do not lie down for at least 30 minutes. These side effects may worsen if you continue to take OSTEONATE 70 mg after developing these symptoms. Do not suck or chew the tablet as it may cause burning in the mouth and throat
- if you have been told by your doctor that you have low blood calcium or a vitamin D deficiency
- if you experience bone, joint or muscle pain whilst taking OSTEONATE 70 mg
- you have been told you have trouble absorbing minerals in your stomach or intestines (malabsorption syndrome)
- if you experience thigh, hip or groin pain (an indication of possible atypical thigh bone fracture)
- if you suffer from kidney disease as you should not take OSTEONATE 70 mg (see Do not take OSTEONATE 70 mg).

Other medicines and OSTEONATE 70 mg

Always tell your healthcare provider if you are taking any other medicine. This includes complementary or traditional medicines.

- do not take any mineral supplements or antacids, containing aluminium, magnesium, iron or calcium and certain laxatives with OSTEONATE 70 mg as it will decrease the absorption of the

OSTEONATE 70 mg in the stomach. Make sure that your daily multivitamin supplement does not contain calcium, aluminium, magnesium or iron

- if you are taking a class of antibiotics called aminoglycosides
- certain medicines called non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, may interfere with how OSTEONATE 70 mg works and cause digestive problems. Caution should therefore be exercised if you take OTEONATE 70 mg and NSAIDs at the same time.

OSTEONATE 70 mg with food and drink

It is important to take OSTEONATE 70 mg with a full glass of water only (not mineral water) in the morning at least 30 minutes before taking any other food, beverages or any other medicines.
It is likely that food and beverages (including mineral water and milk) will make OSTEONATE 70 mg less effective if taken at the same time.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using OSTEONATE 70 mg.

Driving and using machines

OSTEONATE 70 mg has no or negligible direct influence on the ability to drive and use machines. However, certain side effects (for example blurred vision, dizziness and severe bone muscle or joint pain) have been reported while taking OSTEONATE 70 mg.
It is not always possible to predict to what extent OSTEONATE 70 mg may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which OSTEONATE 70 mg affects them.

OSTEONATE 70 mg contains sodium

OSTEONATE 70 mg contains less than 1 mmol sodium (0,023 g) per tablet, that is to say essentially 'sodium free'.

3. How to take OSTEONATE 70 mg

Do not share medicines prescribed for you with any other person.

Always take OSTEONATE 70 mg exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults:

The usual dose is one OSTEONATE 70 mg tablet taken once a week.

Follow these instructions carefully to ensure you benefit from OSTEONATE 70 mg:

- choose one day of the week to take your tablet. Every week, take one OSTEONATE 70 mg tablet on that day
- OSTEONATE 70 mg should be swallowed with a full glass of plain water on an empty stomach. Do not take OSTEONATE 70 mg with bottled water, tea, coffee, milk or juice
- to help OSTEONATE 70 mg reach your stomach quickly and to reduce the chance of irritation when swallowing, OSTEONATE 70 mg must be taken at least 30 minutes before any food, beverage or any other medication
- swallow the tablet whole. Do not suck or chew the tablet
- do not take any milk, antacid or aluminium-, magnesium-, iron-, calcium products or certain types of laxatives with OSTEONATE 70 mg as it will decrease the absorption of the OSTEONATE 70 mg in the stomach
- do not lie down for at least 30 minutes after you have taken OSTEONATE 70 mg and do not lie down until you have eaten
- do not take OSTEONATE 70 mg at bedtime or before getting up in the morning.

It is important to follow the above instructions to reduce the risk of side effects related to the oesophagus (food pipe) e.g. irritation, inflammation or ulceration.

Your doctor may tell you to take calcium and/or vitamin D supplements whilst you are taking OSTEONATE 70 mg.

Children

The safety and effectiveness of OSTEONATE 70 mg in children have not been established.

Your doctor will tell you how long your treatment with OSTEONATE 70 mg will last. Do not stop treatment early.

If you have the impression that the effect of OSTEONATE 70 mg is too strong or too weak, tell your doctor or pharmacist.

If you take more OSTEONATE 70 mg than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of overdose may include:

- upset stomach, heartburn, throat or digestive problems, ulcers.

Taking milk or antacids may help relieve the symptoms.

Do not make yourself vomit, as it may cause irritation or pain on the oesophagus (food pipe).

If you forget to take OSTEONATE 70 mg

If you forget to take OSTEONATE 70 mg, take the missed dose on the morning after you remember. Do not take two tablets on the same day. You should then return to taking one tablet once a week on the same day as originally scheduled.

If you stop taking OSTEONATE 70 mg

It is important that you take OSTEONATE 70 mg for as long as your doctor prescribes the medicine. Since it is not known how long you should take OSTEONATE 70 mg, you should discuss the need to stay on this medicine with your doctor periodically to determine if OSTEONATE 70 mg is still right for you.

4. Possible side effects

OSTEONATE 70 mg can have side effects.

Not all side effects reported for OSTEONATE 70 mg are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using OSTEONATE 70 mg, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using OSTEONATE 70 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to OSTEONATE 70 mg. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- changes in the way your heart beats, for example, if you notice it is beating faster
- heartburn; difficulty swallowing; pain upon swallowing; ulceration of the gullet (oesophagus – the tube that connects your mouth with your stomach) which can cause chest pain, heartburn or

difficulty or pain upon swallowing

- kidney failure: you may experience less urine than is normal for you, swelling of legs, ankles or feet, nausea or extreme tiredness
- toxic epidermal necrolysis (TEN) (a life-threatening skin disorder with symptoms such as a painful red area that spreads quickly, skin peeling without blisters, raw areas of skin) or Stevens-Johnson syndrome (a life-threatening skin disorder with symptoms such as a red-purplish rash and blisters)
- pain in the mouth, and/or jaw, swelling or sores inside the mouth, numbness or a feeling of heaviness in the jaw, or loosening of a tooth. These could be signs of bone damage in the jaw (osteonecrosis) generally associated with delayed healing and infection, often following tooth extraction. Contact your doctor and dentist if you experience such symptoms
- bone, muscle and/or joint pain which is sometimes severe.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache
- abdominal pain, indigestion, bloated or swollen stomach, constipation, diarrhoea, wind, acid regurgitation from the stomach
- skin rash or redness
- muscle cramp, bone, muscle or joint pain
- vertigo (the feeling of moving or spinning while you aren’t moving).

Less frequent side effects:

- cancer of the oesophagus
- symptoms of low blood calcium levels including muscle cramps or spasms and/or tingling

sensation in the fingers or around the mouth

- changes in your sense of taste, dizziness
- inflammation of the eye, redness or pain of the eye, abnormal or blurred vision, double vision, swelling around the eyes
- osteonecrosis of the external auditory canal (a rare medical condition in which a loss of blood flow to the tympanic bone causes bone tissue death, characterised by exposed bone)
- nausea, gastritis, vomiting, black or tar-like stools, oesophagus ulcers, holes in the oesophagus, stomach ulcers, bleeding ulcer
- liver problems, such as yellowing of skin and eyeballs (jaundice), pain in your upper right abdomen, abdominal swelling or generally feel unwell
- hair loss, itching of the skin, sensitivity to sunlight, skin rash
- joint swelling, swelling of your lower legs or hands
- temporary flu-like symptoms (muscle/joint pain, generally feeling unwell and in rare cases fever) usually at the start of treatment
- unusual fracture of the thigh bone particularly in patients on long-term treatment for osteoporosis may occur rarely. Contact your doctor if you experience pain, weakness or discomfort in your thigh, hip or groin as this may be an early indication of a possible fracture of the thigh bone.

The following side effects have been reported but the frequency for them to occur is not known:

- low blood calcium levels.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor ,pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP

(Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of OSTEONATE 70 mg. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store OSTEONATE 70 mg

Store all medicines out of reach of children. Store at or below 25 °C

Protect from moisture and direct light.

Keep blisters in outer carton until required for use.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What OSTEONATE 70 mg contains:

The active substance is alendronic acid.

Each OSTEONATE 70 mg tablet contains trihydrate monosodium alendronate which is equivalent to alendronic acid 70 mg.

The other ingredients are:

Crospovidone, magnesium stearate and microcrystalline cellulose.

What OSTEONATE 70 mg looks like and contents of the pack

OSTEONATE 70 mg tablets are white, oval, flat, which dimensions are 14 x 8 mm and marked on one face with “70”.

OSTEONATE 70 mg tablets are available in an OPA/Al/PVC/Al blister pack containing 4 tablets in an outer carton.

Holder of Certificate of Registration

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